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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte STEFAN GOLZ,
ULF BRUGGEMEIER,
and
ANDREAS GEERTS,
Appellants

Appeal 2008-3673
Application 10/528,460[1]
Technology Center 1600

Decided: 7 July 2008

Before CAROL A. SPIEGEL, TONI R. SCHEINER, and
MARK NAGUMO, *Administrative Patent Judges.*

SPIEGEL, *Administrative Patent Judge.*

DECISION ON APPEAL

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[1] Application 10/528,460 ("the 460 application"), "Diagnostics and Therapeutics for Diseases Associated with Human Phosphodiesterase 11A (PDE11A)," filed 19 December 2005, is a national stage (35 U.S.C. § 371) of international application PCT/EP03/10376, filed 18 September 2003, which is said to claim benefit of the 24 September 2002 filing date of European application 02021365.8. The real party in interest is said to be Bayer Healthcare, AG (Brief on Appeal, filed 4 September 2007 ("Br.") 1).

I. Statement of the Case

Appellants appeal under 35 U.S.C. § 134 from a final rejection of all pending claims, claims 1 and 4-11. We have jurisdiction under 35 U.S.C. § 6(b). We REVERSE and enter a NEW GROUND OF REJECTION.

The subject matter on appeal is directed to a method of screening for a candidate therapeutic agent potentially useful for treating cardiovascular disease based on the agent's ability to bind a human phosphodiesterase 11A (PDE11A) polypeptide. Claim 1 is illustrative and reads (Br., Appendix 1, i):

> 1. A method of screening for candidate therapeutic agents, comprising steps of:
>
> i) contacting a test compound with a PDE11A polypeptide,
>
> ii) detecting binding of said test compound to said PDE11A polypeptide, and
>
> iii) identifying the test compound as a candidate therapeutic agent useful in the treatment of a disease selected from the group consisting of disorders of the peripheral and central nervous system, cardiovascular diseases, cancer, liver disease, and genitourinary disease if the test compound binds to said PDE11A polypeptide.

In response to an election of species requirement in the Office action of August 28, 2006, Appellants elected cardiovascular disease as the disease potentially treated by the candidate agent (Response to Restriction Requirement filed September 21, 2006). There is no indication in the record that the election of species requirement has been withdrawn. Thus, only

methods including the identification of candidates for the prevention of cardiovascular disease are before us for review on appeal.

The Examiner has rejected claims 1 and 5-9 under 35 U.S.C. § 102(b) as anticipated by Yuasa;[2] and claims 1 and 4-11 under 35 U.S.C. § 103(a) as obvious over Yuasa and Lanfear[3] (Ans.[4] 2-4).

II. Discussion

A. Legal principles

Anticipation requires a prior art reference to describe every limitation in a claim either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

A claimed invention is not patentable if it would have been obvious to a person of ordinary skill in the art. 35 U.S.C. § 103(a); *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727 (2007); *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966). Facts relevant to a determination of obviousness include: (1) the scope and content of the prior art, (2) any differences between the claimed invention and the prior art, (3) the level of ordinary skill in the art and (4) relevant objective evidence of nonobviousness. *KSR*, 127 S.Ct. at 1734; *Graham*, 383 U.S. at 17-18. All claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 984 (CCPA 1974).

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[2] K. Yuasa et al., "Isolation and Characterization of Two Novel Phosphodiesterase PDE11A Variants Showing Unique Structure and Tissue-specific Expression," *The Journal of Biological Chemistry*, Vol. 275, No. 40, pp. 31469-31479 (2000) ("Yuasa").

[3] US Patent Application Publication 2002/0115176 A1, "Phosphodiesterase Enzymes," by J. Lanfear et al., published 22 August 2002, based on application 09/321,801, filed 27 May 1999 ("Lanfear").

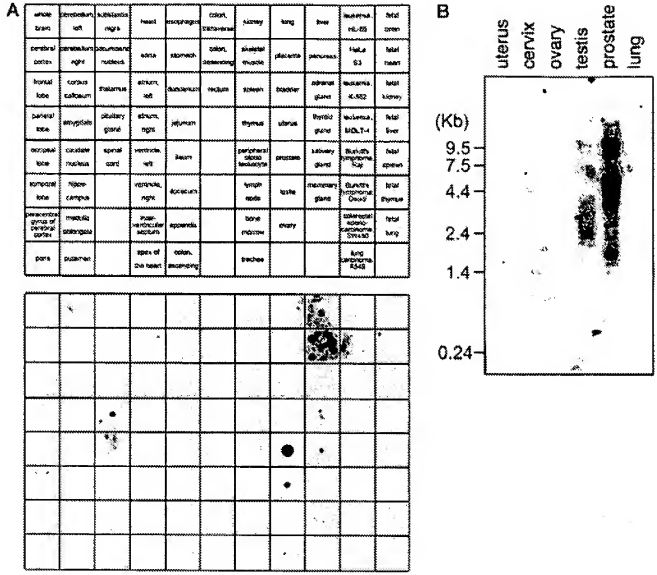
[4] Examiner's Answer mailed 27 November 2007 ("Ans.").

B. Rejections based on Yuasa

The Examiner found that "Yuasa teaches tissue specific (including heart tissue) expression patterns of PDE11A in Figs. 4 & 5 on page 31475" (Ans. 6). The Examiner's finding of anticipation and conclusion of obviousness is based on this finding.

Appellants argue, "There is no disclosure in Yuasa of a connection between PDE11A and the examined species of cardiovascular disease. Thus, Yuasa neither expressly nor inherently anticipates independent claim 1 or its dependent claims 5-9" (Br. 6). Appellants argue further that because, in their view, Lanfear does not provide the missing teaching, claims 1 and 4-11 are not obvious over the combined teachings of Yuasa and Lanfear (Br. 8).

Yuasa Figure 4, said to show the expression of human PDE11A transcripts in various tissues by dot blot (A) and Northern blot (B) analysis, is reproduced below:



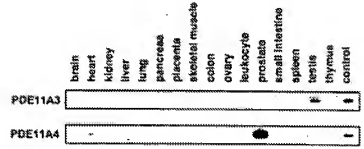
{Yuasa Figure 4 shows the expression of human PDE11A transcripts in various tissues by dot blot (A) and Northern blot (B) hybridization analyses.}

According to Yuasa, moderate expression of PDE11A was observed in testis, salivary gland, pituitary gland, thyroid gland, and liver (Yuasa

31474, ¶ 3) as indicated by the dark spots on the plates in the columns of the corresponding tissues. The fourth column from the left of Yuasa Figure 4(A) contains "dots" of mRNA from various cardiovascular tissues. The tissue "dots," from top to bottom of the column, are heart, aorta, left atrium, right atrium, left ventricle, right ventricle, interventricular septum, and apex of the heart. No darks spots—i.e., no positive hybridization reaction—are evident with any tissue dot in column four of Yuasa Figure 4(A).

Yuasa Figure 4(B) depicts a Northern blot hybridization analysis of mRNA samples from uterus, cervix, ovary, testis, prostate, and lung. No mRNAs from any cardiovascular tissue was tested in the depicted Northern blot hybridization analysis.

Yuasa Figure 5, depicting testing for expression of two variants of PDE11A in various tissues, including heart, by Southern blot hybridization analysis, is reproduced below:



{Yuasa Figure 5 detects expression of two PDE11A variants, PDE11A3 (top) and PDE11A4 (bottom), by Southern blot hybridization analysis.}

Neither PDE11A variant is expressed in heart tissue according to Yuasa Figure 5. According to Yuasa, "PDE11A3 transcripts were specific in testis, whereas PDE11A4 transcripts were particularly abundant in prostate (Fig. 5)" (Yuasa 31474, ¶ 4).

Since neither Yuasa Figure 4 nor 5 teaches or suggests that PDE11A transcripts are expressed in cardiovascular tissues, we reverse the rejection of claims 1 and 5-9 as unpatentable under § 102 in view of Yuasa and the rejection of claims 1 and 4-11 as unpatentable under § 103 in view of Yuasa and Lanfear.

III. New Ground of Rejection

We enter the following new ground of rejection pursuant to 37 C.F.R. § 41.50 (b). Claims 1, 4 and 10 are rejected under 35 U.S.C. § 102(b) as anticipated by Lanfear.

Lanfear discloses

> a method of screening an agent for specific binding affinity with PDE11 (or a derivative, homologue, variant or fragment thereof) . . . comprising the steps of: a) providing a candidate agent; b) combining PDE11 (or a derivative, homologue, variant or fragment thereof . . .) with the candidate agent for a time sufficient to allow binding under suitable conditions; and c) detecting binding of the candidate agent to PDE11 (or a derivative, homologue, variant or fragment thereof) . . . in order to ascertain if the candidate agent binds to PDE11 (or a derivative, homologue, variant or fragment thereof) . . . . [Lanfear ¶ 519.]

According to Lanfear

> A PDE11A polypeptide . . . can be used for screening therapeutic compounds in any of a variety of drug screening techniques. The polypeptide employed in such a test may be free in solution, affixed to a solid support, borne on a cell surface, or located intracellularly. The . . . formation of binding complexes between an

> PDE11 polypeptide and the agent being tested may be measured. [Lanfear ¶ 524.]

"For example, anti-PDE11 antibodies capable of neutralizing the activity of PDE11 may be used to inhibit PDE11 hydrolysis of cyclic nucleotides, thereby decreasing their levels" (Lanfear ¶ 521). Lanfear further discloses "use of an agent to affect PDE11 activity (such as to inhibit, modulate or agonise) in the striatum of the brain, which is a region known to be affected in neurological diseases or conditions, including . . . Alzheimer's Disease, Parkinson's Disease, and Huntington's Disease, . . ." (Lanfear ¶ 532).

Independent claim 1 is directed to a method of "screening for candidate therapeutic agents." The method of claim 1 has three steps: i) contacting a test compound with a PDE11A polypeptide, ii) detecting if the test compound binds to the polypeptide, and iii) if binding occurs, "identifying"—i.e., classifying— the test compound as a candidate, i.e., *potential*, therapeutic agent to treat certain enumerated diseases. The first two method steps are essentially data gathering steps. The third method step merely recites the purpose or intended use of the claimed method, i.e., to identify a *potential* therapeutic agent to treat certain diseases. Thus, the third step is fully met by the purely mental step of recognizing that binding may indicate the potential utility of the test compound for treatment of a disease involving the PDE11A that was tested. The third method step does not require performing any actions to test whether or verify that the compound is capable of treating one of the diseases enumerated in the claim. Therefore, we conclude that step iii) of claim 1 is entitled to little, if any, patentable weight.

However, we find that the method of claim 1 is anticipated by Lanfear regardless of the patentable weight accorded to step iii) of claim 1. Lanfear teaches screening for therapeutic compounds, such as neutralizing antibodies, which bind to PDE11 or a variant thereof and using compounds which affect PDE11 activity in the striatum of the brain, such as a neutralizing antibody which inhibits PDE11 activity, to treat disorders of the peripheral and central nervous system (Lanfear ¶¶ 519, 521, 524, and 532).

Claim 4 requires the contacting step to occur "in or at the surface of a cell." Claim 10 requires the PDE11A polypeptide to be attached to a solid support. Lanfear teaches these limitations as well (Lanfear ¶ 524).

We leave it to the Examiner to determine the applicability of Lanfear and other prior art to claims 5-9 and 11.

IV. Order

Upon consideration of the record, and for the reasons given, it is

ORDERED that the Examiner's decision to reject claims 1 and 5-9 under 35 U.S.C. § 102(b) as unpatentable over Yuasa is REVERSED;

FURTHER ORDERED that the Examiner's decision to reject claims 1 and 4-11 under 35 U.S.C. § 103(a) as unpatentable over Yuasa in view of Lanfear is REVERSED; and,

FURTHER ORDERED that a new ground of rejection is entered against claims 1, 4 and 10 under 35 U.S.C. § 102(b) as unpatentable over Lanfear.

Section 41.50(b) also provides that *WITHIN TWO MONTHS FROM THE DATE OF THE DECISION*, Appellant must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. . . .
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record. . . .

Should Appellant elect to prosecute further before the examiner pursuant to 37 C.F.R. § 41.50(b)(1), in order to preserve the right to seek review under 35 U.S.C. §§ 141 or 145 with respect to the affirmed rejection, the effective date of the affirmance is deferred until conclusion of the prosecution before the Examiner unless, as a mere incident to the limited prosecution, the affirmed rejection is overcome.

If Appellant elects prosecution before the Examiner and this does not result in allowance of the application, abandonment or a second appeal, this case should be returned to the Board of Patent Appeals and Interferences for final action on the affirmed rejection, including any timely request for rehearing thereof.

REVERSED; 37 C.F.R. § 41.50(b)

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